

K813052 ULTRACAST WATERLESS SYNTHETIC RESIN CASTFeb 4, 1982
98 days to decisionK813052 · Product code: **ITG** · Physical Medicine
Source: <https://www.510kdatabase.net/k813052/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Bandage, Cast (ITG)
Date received	Oct 29, 1981
Decision date	Feb 4, 1982
Days to decision	98 days
Third-party review	No

APPLICANT

Company	Zimmer, Inc.
Location	Warsaw, IN, US
Website	https://www.zimmerbiomet.com
510(k) history	374 submissions · 353 cleared · 1976-2026

Zimmer, Inc. is a leading orthopedic medical device manufacturer based in Warsaw, US. The company specializes in innovative surgical implants and trauma solutions. Zimmer, Inc. maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions since 1976. Orthopedic devices represent approximately 90% of the company's submission portfolio. The company remains actively engaged in product development, with the latest FDA 510(k) clearance in 2026. Recent cleared devices reflect the company's focus on joint reconstruction and trauma fixation. Notable ...